CORRELATIONS BETWEEN ORAL HEALTH KNOWLEDGE, LOCUS OF CONTROL, AND ORAL HEALTH STATUS

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MASTER'S THESIS

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ABSTRACT

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Introduction: Patient intervention plays an important role in management of oral diseases, such as caries and periodontitis. Understanding dynamics of a person's behavior is a complex area of study that, if better understood, could result in improved oral health. Oral Health knowledge (OHK) and Multidimensional Health Locus of Control-Form C, a predictor of behavior for specific health conditions, are two measurable determinants that may affect oral health status (OHS). The Survey of Oral Health Knowledge in Adults (SOHKA) was developed to comprehensively assess OHK. To date, no study has been performed to evaluate if oral disease specific Locus of Control and comprehensive OHK have any effect on OHS.

Objectives: To study (1) the reliability and validity of SOHKA as a measure OHK, (2) OHK and Locus of Control in active duty personnel, (3) the association of OHK and Locus of Control with OHS.

Methods: A total of 868 subjects will complete three questionnaires: (1) demographic/behavior, (2) Locus of Control specific for oral diseases, and (3) the SOHKA for OHK via web based survey. Dental records from 556 subjects will simultaneously be reviewed for caries risk, periodontal risk and 3 years caries incidence.

Results: The research protocol is just approved by WRNMMC IRB. No data is available to analyze.

Conclusions: Oral diseases are prevalent problems affecting the general and military population. Utilizing Locus of Control and the SOHKA could provide the potential to promote positive oral health behaviors, and enhance the educational interventions and disease management that affect individual oral health, and ultimately operational readiness. The data may indicate that patients identified with low dental knowledge and more external locus of control have increased oral disease risk and poorer health status.

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LIST OF ABBREVIATIONS

1. deft	Decayed, Extracted, Filled Teeth (primary teeth)
2. DMFT	Decayed, Missing, Filled Teeth (permanent teeth)
3. NHANES	National Health and Nutrition Examination Survey
4. IOM	Institute of Medicine
5. CDC	Center of Disease Control
6. ADA	American Dental Association
7. NIH	National Institute of Health
8. WHO	World Health Organization
9. AMA	American Medical Association
10. TOFHLA	Test of Functional Literacy in Adults
11. TOFHLA-s	Short version- Test of Functional Literacy in Adults
12. WRAT	Wide Range Achievement Test
13. REALM	Rapid Estimate of Adult Literacy in Medicine
14. REALD-30	Rapid Estimate of Adult Literacy in Dentisty-30
15. CMOHK	Comprehensive Measure of Oral Health Knowledge
16. OHLi	Oral Health Literacy
17. TOFHLiD	Test of Functional Health Literacy in Adults Dentistry
18. HFQOL	Heart Failure-Related Quality of Life
19. TTM	Transtheoretical Model
20. HBM	Health Belief Model
21. TPB	Theory of Planned Behavior

22. SLT	Social Learning Theory
23. LOC	Locus of Control
24. HLC	Health Locus of Control
25. MHLC	Multidimensional Health Locus of Control
26. IHLC	Internal Health Locus of Control
27. PHLC	Powerful Others Health Locus of Control
28. CHLC	Chance Health Locus of Control
29. DHLC	Doctors Health Locus of Control
30. OHLC	Others Health Locus of Control
31. SOHKA	Survey or Oral Health Knowledge in Adults
32. OHIP-14	Oral Health Impact Profile

CHAPTER I: INTRODUCTION

Since the introduction of fluoride into public drinking water during the 1940s and 1950s, the prevalence of dental caries among the world's population has drastically decreased. One example, observed in Grand Rapids, Michigan, showed a reduction of approximately 60% in the number of decayed, extracted, or filled teeth (DMFT) among children over a 10-year period (Dean, Arnold, Jay & Knutson, 1956). Over the last few decades, dentistry has made progress in its management and prevention of patients with dental caries. Along with the addition of fluoride to public drinking supplies, fluoride-releasing materials were introduced in 1972 (Wilson & Kent, 1972), a paradigm switch occurred from treatment of dental caries with a surgical model to one facilitated by disease prevention (Anderson, Bales, & Omnell, 1993), and health literacy became nationally recognized as a contributor to health outcomes to both general and oral health (Healthy People 2000).

Despite these philosophical, technological, and cognitive advances in general health and dentistry, chronic diseases, such as dental caries, are still prevalent among our population today. From 1971 to 1985, the number of DMFT decreased by 20% among working adults ages 18-34. However, a mean DMFT of approximately 10 was recorded in this population (Brown & Swango, 1993). According to National Health and Nutrition Examination Survey (NHANES) data collected between 1999 and 2004, 92% of adults, aged 20-64, experienced dental caries, with a mean DMFT of 3.28 (NHANES survey 1999-2004). Dental caries is particularly rampant among new U.S. Air Force, Army, Navy and Marine Corps recruits. According to a 2008 evaluation of 5,385 recruits at 9 military installations across the U.S., on average, each new recruit needed 3.4 dental restorations upon accession into military service. Moreover, fewer than 28% presented

with no restorative need, while over 14% required seven or more restorations (Leiendecker, Martin & Moss, 2011).

As a result of the widespread caries prevalence among global, U.S., and U.S. military populations, organizations such as the Institute of Medicine (IOM), Center for Disease Control and Prevention (CDC), American Dental Association (ADA), National Institute of Health (NIH), World Health Organization (WHO), and Department of the Navy have developed and dedicated missions, research, and goals towards the reduction of oral diseases. As stated in Health People 2020, "Oral Health is essential to overall health. Good oral health improves a person's ability to speak, smile, smell, taste, touch, chew, swallow, and make facial expressions…good self-care…is key to good oral health."

Further comprehension of oral health literacy is just one preventative course that can lead progression to better oral health status. In a 2011 report, *Advancing Oral Health in America*, an Institute of Medicine committee identified the following guiding principles for the Human Health Services that will foster growth in this field of dentistry: (1) emphasize disease prevention and oral health promotion; (2) improve oral health literacy and competence; and (3) expand oral health research and improve data collection (Institute of Medicine, 2011).

Understanding dynamics of a person's behavior is another course of study that, if understood better, could result in better oral health. Professionals in the medical, psychological, behavioral, and dental fields have attempted to study and understand the variables surrounding health literacy and behavior, in hope of improving patients' overall health. However, the relationship between health literacy and the factors governing

health status has proved to be extremely complex, involving a myriad of factors at the self-care, health care, and patient-provider level (Paasche-Orlow & Wolf, 2007). Despite the complexity, health literacy, behavior, and general health outcomes have been heavily researched, leading to a greater understanding of the extent of this relationship. This is not the case, however, when it comes to understanding the determinants of oral health outcomes. Consequently, more research is necessary to understand the factors that contribute to oral health outcomes. Locus of Control provides practitioners with one determinant of behavior.

It is academically accepted that knowledge is a component of health literacy and can be ascribed as a factor in several health literacy/behavior models (Ryan, 2009; Macek & Colleagues, 2010; Ory, Smith, Mier & Wernicke, 2010; Osborn, Paasche-Orlow, Bailey & Wolf, 2011; Sun, & Colleagues, 2013; Dunutrescu, Wagle, Dogaru & Manolescu, 2011; Paasche-Orlow & Wolf, 2007; Baker, 2006). However, within oral health literacy studies, knowledge provides the "weakest relationship" to oral health outcomes (Citro, 2013). This weak relationship may be due to the methods by which oral health knowledge is measured. Citro contended that prior studies measuring oral health knowledge either measured attitude, or the questionnaire was not inclusive enough to properly assess knowledge. Therefore, if knowledge can be assessed comprehensively, along with greater understanding of the relationships amongst attitude, behavior, and oral health status, we may advance our understanding of this complex issue and enhance the educational interventions that affect individual oral health.

CHAPTER II: REVIEW OF LITERATURE

Health Literacy

Health literacy, as defined by Healthy People 2010, is "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions." In 1998, American Medical Association (AMA) became one of the first medical institutions to recognize that health literacy influences the diagnosis and treatment of patients (AMA: Health Literacy Program). The association of low health literacy to poor health outcomes led organizations such as the AMA to dedicate resources to improving health literacy among the U.S. population. Even though there has been a large movement to increase health literacy and diminish the effects that occur when literacy is low, poor health literacy remains widespread. An estimated 90 million people lack the literacy to perform basic health care actions (Institute of Medicine, 2004), costing an additional estimated 60 to 230 billion dollars annually. Poor health literacy furthermore influences preventative care use (Scott, Gazmararian, Williams, & Baker, 2002), rate of hospitalizations (Baker, Parker, Williams, & Clark, 1998), and higher health care costs (Howard, Gazmararian, & Parker, 2005).

Researchers have developed and studied numerous interventions to improve health literacy and health status. Interventions consist of educational strategies that incorporate brochures, videos, educational programs, and counseling. A 2004 systematic review studied various methods to reduce adverse outcomes in patients with low literacy. After reviewing 20 articles, in which knowledge was measured consistently, the authors determined that "limitations in design, instruments tested, and outcomes make drawing any conclusions about effectiveness difficult" (Pigone, Dewalt, Sheridan, Berkman &

Lohr, 2004). Consequently, more research is needed to understand the relationship between health literacy and outcomes. To date, health literacy has been predominately measured utilizing three tests: (1) Test of Functional Health Literacy in Adults (TOFHLA; Parker, Baker, Williams & Nurss, 1995) or short version (S-TOFHLA; Baker, Williams, Parker, Gazmariarian & Nurss, 1999); (2) Wide Range Achievement Test (WRAT4; Wilkinrson & Robertson, 2006); and (3) Rapid Estimate of Adult Literacy in Medicine (REALM; Davis, Long & Jackson, 1993). These tests and others assess health literacy by measuring word recognition, reading comprehension and pronunciation.

Since 1998, researchers executed multiple systematic reviews regarding the topic of health literacy. In particular, patients with lower reading aptitude were 1.5 to three times more likely to have adverse health outcomes (Dewalt, Berkman, Sheridan, Lohr & Pigone, 2004). There are additional studies associating low health literacy with diminished health status (Baker, Parker, & Clark, 1997; National Center for Education Statistics, 2006). However, the impact of current health literacy measurements on health status "may go beyond his or her ability to understand written or even spoken instruction." These measurements constitute a fraction of the factors associated with decreased health status (Berkman & colleagues, 2004).

Health literacy has also been linked to poorer health-related knowledge and utilization of health care services (Berkman, Sheridan, Doahue, Halpern & Crotty, 2011; Dewalt & colleagues, 2004). The poor utilization of health services results in higher expenditures (Potter & Martin, 2005). Poor utilization of health care services also affects the dental community and subsequently impacts the medical community. According to

the National Hospital Ambulatory Medical Care Survey, dental visits to emergency rooms nearly doubled from 2000 to 2010, approximating 2.1 million encounters. Additionally, during the same time period, the percentage of dental realated encounters in all emergency room visits was observed. It increased from 1.06 percent to 1.65 percent, costing the health care system up to 2.1 billion dollars in 2010 (Soderlund, 2013). These costs may also transfer indirectly through the associations of oral diseases with cardiovascular disease (Neese, Dijkstra & Abbas, 2010), pregnancy (Bobetsis, Barros & Offenbacher, 2006), and diabetes (Measley, 2006).

Many studies have quantified the prevalence of poor health literacy in the general population. However, the prevalence of low oral health literacy has yet to be extensively reported in the literature. Jones, Lee and Rozier (2007) administered the Rapid Estimate of Adult Literacy in Dentistry-30 (REALD-30) to 101 patients in two private practices, and determined that 29% of the patients had low oral health literacy. Hom and colleagues (2012) administered the REALD-30 to 119 low-income patients who were pregnant for the first time; 23% of the participants' scores equated to low oral health literacy.

Cohen, Bonito and Eicheldinger (2011) results suggest that the problem of oral health literacy is not as significant as it is in general medicine. They delivered a survey to 423 patients who sought emergency dental care. Of those surveyed, only 10% reported having difficulty understanding the provider. This percentage is small compared to the weighted prevalence of approximately 26% with low health literacy in the United States (Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman & Rudd, 2005). This is attributed to reduced complexity and less demand from the patient in terms of

management, compared to medical conditions (Research Activities, March 2012). Furthermore, poor to moderate correlations exist between: (1) TOFHLA and Comprehensive Measure of Oral Health Knowledge (CMOHK; Macek & colleagues, 2010) and (2) Test of Functional Health Literacy in Adults Dentistry (TOFHLiD) and TOFHLA/REALM (Gong & colleagues, 2007). General health literacy tests also show poor association with oral health outcomes, perhaps because these tests do not evaluate dental knowledge or exposure to dental health care (Richman & colleagues, 2007). This suggests determinants of oral health outcomes and general health outcomes may be two distinct entities and should be studied and measured separately.

In 2000, the U.S. Surgeon General described the condition of oral health in the nation as a "silent epidemic" (U.S. Department of Health and Human Services, 2000). While there has been improvement in oral health status among the U.S. population, the number of citizens with poor oral health remains disconcerting. Low oral health literacy, compounded with other barriers, plays a large role in the overall poor oral health status of the nation (NIDCR, 2005). Health literacy is a dynamic process involving not only individual factors such as reading, knowledge, and comprehension ability, but is also affected by socioeconomic status, education, culture and norms (Baker, 2006), patient-provider communication (Paasche-Orlow & Wolf, 2007; Macek & colleagues, 2010), and self-regulation and decision making (Ryan 2009; Macek & colleagues, 2010). These additional variables make studying literacy and implementing policy very difficult. Horowitz and Kleinman (2012) described oral health literacy as "an intricate process of acquiring and trusting information, skill development, grasping concepts, and technique-intensive protocols, and applying them appropriately." Even though health literacy is

difficult to measure and improve in individuals, both medical and dental professionals accept it as a barrier to patients' abilities to seek care and make knowledgeable decisions affecting their overall health outcomes. Poor literacy also constrains patient-provider communication (Macek & colleagues, 2010; Baker, 2006), which, in turn, hinders the "prevention, diagnosis, and treatment of oral diseases" (American Dental Association, 2009).

Most oral health literacy studies have measured individual capacities (reading fluency and vocabulary) and the influence of external factors (socioeconomic status, education, sex, and age), on literacy, rather than the modifiers of behavior (beliefs, self-efficacy, knowledge, motivation, and problem solving ability) that ultimately impact health status. One of the weakest relationships is between knowledge and oral health status (Citro, 2013), even though knowledge appears to play a large role in both general and oral health literacy models. Macek and colleagues (2010), Baker (2006), and others (Paasche-Orlow & Wolf, 2007; Ryan, 2009) attribute knowledge as a factor linked with improving a patient's health outcome.

Knowledge

Knowledge defined by the Merriam-Webster Dictionary is the "information, understanding, or skill that you get from experience or education." In the context of health or oral health, knowledge has been described as "condition-specific factual information" (Ryan, 2009) and "the confident understanding of a subject with the ability to use it for a specific purpose" (Sharda & Shetty, 2008).

Throughout general health literacy studies, the trend shows a positive correlation and statistically significant relationship between literacy and knowledge of numerous

health complications (Berkman, Sheridan, Doahue, Halpern & Crotty, 2011; Berkman & colleagues, 2004). Therefore, knowledge has been incorporated and described as a determinant of health literacy (IOM, 2004; Baker, 2006). Low literacy affects not only the comprehension of disease-specific facts, but also the knowledge of behaviors associated with management of diseases. This is apparent in studies of patients with asthma (Williams, Baker, Honig, Lee, & Nowlan, 1998) and HIV (Kalichman & Rompa, 2000).

Kalichman and Rompa (2000) studied 339 HIV-infected patients, approximately 25% with low functional health literacy. All patients were measured for health literacy (TOFHLA), health status (self-reported and laboratory cluster of differentiation 4 (CD4) count), and knowledge. A 14-question survey testing knowledge regarding transmission, disease process, medication use, and viral loads was administered. Low health literacy was associated with both inferior knowledge and poorer health status (lower CD4 counts, higher viral load). Further, patients with low health literacy were less likely to consume their prescribed medications.

Low health literacy (REALM) has also been directly correlated with poor dental knowledge (Macek & colleagues, 2010). Macek and colleagues provided a questionnaire comparing the REALM, s-TOFHLA, and Comprehensive Measure of Oral Health Knowledge (CMOHK) to 100 participants. The population demographics consisted of 92% African Americans, 55% females, and 51% with an income under $25,000. REALM and CMOHK were statistically associated with each other ($p<0.01$), however, s-TOFHLA ($p=0.62$) was not significant. When observing demographic variables, CMOHK scores were statistically associated with both education ($p<0.01$) and age

($p<0.01$). Hom and colleagues (2012) studied the relationship between oral health literacy (REALD-30) and oral health knowledge (six-question survey) among 119 pregnant females. They found an overall positive correlation ($p<0.01$) between high levels of knowledge (low = 0-2; high = 5-6 survey questions answered correctly) and high REALD-30 scores. Specifically, two knowledge questions regarding fluoride use and spread of infections were statistically associated ($p<0.01$) with higher REALD-30 scores. Additional studies also support the association of dental knowledge and oral health literacy (Vann, Lee, Baker & Divaris, 2010; Jones, Lee & Rozier, 2007). Jones and colleagues studied oral health literacy among an adult population ($n=101$) in North Carolina. The survey contained the REALD-30, REALM, and a 23-question section measuring components of health literacy, to include dental knowledge. Patients with 'incorrect knowledge' (missed one or more questions regarding dental caries or periodontal disease) were six times more likely to have low literacy than those who answered all questions correctly.

However, recent literature also shows that poor health knowledge can be found in populations of high general and oral health literacy. In a study of 100 patients, data was collected measuring oral health knowledge (17-question survey), TOFHLA, and oral health literacy (OHLI). Of those studied, 87.2% had adequate oral health literacy and 91.7% had adequate functional health literacy (>74% score). Meanwhile, a mean score of 57.5 was reported on the oral health knowledge questionnaire, indicating low oral health knowledge (Sabbahi, Lawrence, Limeback & Rootman, 2009). Despite this contradicting study, the literature predominately reports positive correlations between oral health literacy and oral health knowledge. This relationship has been described as

"bidirectional." A patient with increased literacy will have enhanced individual capabilities, such as reading comprehension and vocabulary, which will increase his ability to grasp complex oral health knowledge. An increase in oral health knowledge has been shown to improve a person's overall oral health literacy (Jones & colleagues, 2007).

The mechanisms by which knowledge affects health status are not well known. Macek and colleagues (2010) proposed a conceptual framework for oral health outcomes that distinguishes four facets of health literacy's linkage to health outcomes: conceptual knowledge, word recognition, reading skills, and decision-making. Decision-making links the relationship between individual skills, such as word recognition, reading comprehension and knowledge, to oral health outcomes. The authors hypothesize that "poor knowledge and reading skills likely influence a myriad of decisions" that ultimately influence health outcomes.

The impact of knowledge on oral health status is limited and results are mixed. Several studies have investigated the relationship between oral health knowledge and oral health status among children and parents. Chu, Ho, and Lo (2012) examined 700 children, ages four to six, with a mean dmft score of 2.2 (sd = 3.5). The parents' dental knowledge was assessed utilizing a 21-item multiple-choice questionnaire. The scores were stratified into three intervals (0 – 7 = "low" dental knowledge; 8 – 14 = "moderate"; 15 – 21 = "high' dental knowledge). A statistically significant correlation ($p < 0.01$) was observed between parents with low dental knowledge and increased caries experience among their children. Conversely, research of 11-year-old children in Canada (n = 6,329) revealed that "high" dental knowledge was associated with low DMFT scores ($p < 0.01$)

and behavior, such as brushing twice daily and using toothpaste (Hamilton & Coulby, 1991). Several other studies have reported statistically significant associations between low oral health knowledge and increased caries experience (Oliveria, Nerendran & Williamson, 2000; Vann & colleagues 2010; Suprabha, Rao, Shenoy & Khanal, 2013). In contrast, Woolfolk, Lang, and Faja (1989) found no correlation between dental knowledge and mean DMFS scores among 848 9- to 12-year-old children in Michigan.

Studies in adults have been less reported in the literature and results are variable. In Australia, 879 adults, aged 45 to 54 years, were surveyed, and majority (>75%) were examined to record DMFT scores. The survey consisted of seven questions, based on a five-point Likert scale, related to prevention of dental caries. Females recorded higher dental knowledge scores (mean = 69.9%) than males (mean = 49.4%). Other variables, such as place of birth, education, and income, were not significantly associated with knowledge. The correlations between oral health status (fewer decayed teeth, $p < 0.05$; more filled teeth, $p < 0.01$) and dental knowledge were statistically significant for both males and females. (Brennan, Spencer & Roberts-Thomson, 2010). Similarly, Ogawa and colleagues (2003) reported that greater knowledge was associated with better oral health status (lower DMFT) among a diverse age group (12 to 74 years) in Myanmar (Burma).

In China, 324 adults, aged 18 years, were assessed for oral health status (DMFT and Community Periodontal Index) and dental knowledge. Each participant answered a four-item dental knowledge questionnaire regarding the causes and prevention of dental caries and periodontal disease. The young adults who had higher knowledge and

practiced preventative behaviors had greater gingival health. Measures of caries status, however, were not significantly associated with dental knowledge (Lu, 2013).

Contradicting the association between dental knowledge and oral health status is a study of periodontal patients. Bader and colleagues (1990) measured the periodontal status (missing teeth, Plaque Index, Gingival Index, calculus index, probing depth, and attachment loss) and periodontal knowledge (26-item, four-point Likert scale questionnaire) of 1,088 adult patients. Greater dental knowledge did not result in lower severity of periodontal disease, especially when race, age, and sex variables were held constant. The study population consisted of patients who regularly attended one of thirty-six selected dental practices. Therefore, the authors discussed the possibility that regular maintenance may be "more determinative" than dental knowledge. Similarly, another study in China (n = 3,088), aged 44-74, observed no association between knowledge and disease status (Lin, Wong, Wang & Lo, 2001).

General Health Behavior

The American Psychological Association defines behavior as "the actions by which an organism adjusts to its environment" (Gerrig & Zimbardo, 2002). Health behavior theorists accept that the "action" must occur before health status can be improved. Although some studies have reported short-term behavior modification with patient education alone (Wade, Coates, Gauld, Livingstone & Cullinan, 2013; Solhi, Zadeh, Seraj, & Zedeh, 2010), others contend that providing or improving knowledge alone will not effect long-term behavioral change (Bodenheimer, 2005; Ryan, 2009).

Chen and colleagues (2013) examined the associations among health literacy, heart failure, knowledge, self-efficacy, and self-care (behavior) among 81 heart failure

patients. The looked to model the various determinants of behavior. The study utilized S-TOFHLA, heart failure knowledge questionnaire (15 questions), and Self-care Heart Failure Index (behavior and self-efficacy. Statistical analysis revealed a positive association among knowledge, health literacy, and formal education ($p < 0.001$). However, these three factors were not significantly associated with behavior (self-care maintenance and management) and self-efficacy. The authors concluded that knowledge and health literacy do not entirely explain a patient's engagement in behavior. Rather, behavior may be dictated by a patient's confidence in performing self care.

Similarly, Macabasco-O'Connell and colleagues (2010) evaluated similar variables along with a measurement of health status (Heart Failure-Related Quality of Life: HFQOL). The questionnaires administered included: (1) TOFHLA; (2) Heart Failure Symptom Scale to measure HFQOL; (3) knowledge and behavior survey, 28 total questions; and (4) a self-developed 10-item self-efficacy scale. Patients ($n = 605$) with more than 'adequate health literacy' (> 22 TOFHLA score) exhibited greater heart failure knowledge ($p < 0.01$), greater self-efficacy ($p < 0.01$), more self-care behaviors ($p < 0.001$), and higher HFQOL scores ($p < 0.01$). Utilizing structural modeling, similar to Chen and colleagues (2013), the relationship of health literacy and HFQOL was analyzed statistically. Low literacy was significantly associated with poorer knowledge, self-efficacy and health status (all p values < 0.05), but less strongly associated with behavior ($p = 0.09$). Statistically analyzing the direct and indirect effects of mediators (knowledge, behavior, and self-efficacy), low literacy and health status were not associated. Rather, low literacy and behavior were mediated by these other factors. This was attributed to

the non-comprehensive measure of behavior, self-efficacy, and behavior because "no instrument can address all aspects of care for an individual."

Paache-Orlow and Wolf's (2007) health literacy model investigated a causal mechanism, modeled after the 'self-care' pathway, linking health literacy to physical activity (behavior), and self-reported health status. Patients (n = 330) with hypertension completed tests for health literacy, knowledge, self-efficacy, behavior, and health status. The results revealed that knowledge and self-efficacy predicted self-reported health status, and behavior predicted health status. However, knowledge was not associated with behavior. According to the study, this is "consistent with behavior change frameworks" (Osborn, Paache-Orlow, Bailey, & Wolf, 2011).

Oral Health Behavior

According to the 1985 National Health Interview survey, knowledge of oral hygiene behaviors is limited. This survey focused on five overarching questions, with multiple sub-questions, regarding caries prevention, gingivitis prevention, causes of tooth loss in children and adults, and knowledge of dental sealants. Approximately 33,600 participants rated the importance of prevention measures (fluoridated water, fluoride toothpaste/rinse, brushing and flossing, in-between meal sweets, seeing a dentist regularly) to prevent dental caries and periodontal disease. A vast majority (88%) regarded brushing and flossing as 'definitely important' to prevent caries. Meanwhile, only 45% and 61%, respectively, deemed fluoridated water and fluoride tooth paste/rinse as 'definitely important.' Fifty-nine percent of respondents stated that avoiding between-meal sweets was important to prevent tooth decay. The importance of all rated self-care behaviors for gum disease was appreciably lower compared to caries prevention. Almost

half of the study population (47%) identified fluoride as 'definitely important' in preventing periodontal disease. These results indicated people "underestimate" the importance of fluoride in caries prevention and do not understand fluoride's mechanistic inability to prevent periodontal disease. However, the authors suggested that, regardless of how well individuals comprehend the mechanisms of oral self-care behaviors, strong positive beliefs in the importance of such behaviors might possibly lead to "good oral hygiene habits" (Corbin, Maas, Kleinman, & Backinger, 1987).

Preventive education is the primary approach to increase awareness of the importance of oral hygiene behaviors and increase oral health status at the individual level. Boehmer, Kressin and Spiro (1999) examined whether the actual engagement in oral hygiene practices resulted in short- and long-term improvements in oral health status. Over 600 men enrolled in the Veterans Administration Dental Longitudinal Study and were observed with dental examinations and questionnaires for self-care behaviors (self-reported), oral health status (functioning teeth, DMFT, tooth health, root-DF), and dental care behaviors (prevention performed by dentist). Utilizing summary scales that measure average frequency of behaviors over a longitudinal period, 15 years of preventative behavior were extrapolated from each patient's last five examination cycles. Results from the study concluded: (1) overall increased frequency of oral self-care behavior (i.e. tooth brushing) generally resulted in significantly improved oral health status measured by functioning teeth, not DMFT; (2) professional prophylaxis was the only behavior consistently associated with all measures of oral health status; (3) tooth brushing was not a predictor of any oral health status measure; and (4) long-term oral health behaviors resulted in improved oral health status.

Health Behavior Theories

In order to attempt to modify and facilitate behavioral change, a multitude of behavior theories have been developed. Some of these models have been applied to health behavior, and include the Social Learning Theory (Rotter, 1954), Health Belief Model (Rosenstock, 1966), Transtheoretical Model (Prochaska & DiClemente, 1982), Theory of Planned Behavior (Ajzen, 1991), and Social Cognitive Theory (Bandura, 1994). These models have demonstrated some success in initiation and prediction of behavior in patients with both chronic and acute health problems within the medical community.

Transtheoretical Model (TTM)

In this model, patients are categorized based on their willingness to change and engage in behaviors along a spectrum of five stages. These five stages of change include: (1) pre-contemplation (not intending to make behavior changes); (2) contemplation (considering change); (3) preparation (making small changes); (4) action (engaging in new behavior); and (5) maintenance (sustaining new behavior over time) (Prochaska & DiClemente, 1982). Patients have the ability to move around the five stages, and the interventions can be adapted depending the current stage the patient is identified in. For example, patients determined to be in the pre-contemplation phase have no intention to modify behavior because they do not believe the benefits outweigh the risks, or they are not aware of the risks. Intervention with a pre-contemplator may include education health risks/benefits via a video or brochure to introduce new knowledge. As patients

progress into later stages, additional support and behavioral education to improve confidence in performing behaviors are required to prevent relapse into prior stages and facilitate progression into maintenance stages.

TTM has shown promise in implementing oral hygiene behavioral change. Wade and colleagues (2013) studied oral hygiene behaviors and the willingness of patients to change. In this study, 105 participants completed a survey evaluating their confidence and frequency of flossing and brushing at baseline, three months, and six months. Immediately following baseline measurements, the patients were given oral hygiene instruction. Of the 33% of subjects who improved their TTM stage at three months, 35% decreased to a lower level. Patients who maintained confidence in their preventative practices exhibited higher TTM stages through the study. The results of this study emphasize the importance of continual reinforcement of preventative behaviors by dental professionals during visits and improving patients' confidence in behaviors

Health Belief Model (HBM)

Rosentock and Hochbaum developed the Health Belief Model (HBM) in the 1950s to explain why patients would not attend medical screening programs for tuberculosis. The original model was based upon the constructs of perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action (Rosenstock, 1966). Since the original model was proposed, other concepts have been included in the model; these include motivating factors and self-efficacy. They account for the knowledge gained about the importance of personal responsibility (Edberg, 2006). Ultimately, the model attempts to use these constructs to explain

people's behavior and derive strategies that will alter detrimental perceptions. Strategies evolve around providing patients with knowledge that will result in preventive behavior participation.

One study surveyed 92 participants (51 females; 41 males; mean age = 41). Each participant completed a HBM survey, evaluating the five factors of susceptibility, severity, benefits, barriers, and self-efficacy, along with a behavior questionnaire to assess brushing and flossing frequency. The results propose that strategies to reduce barriers, along with increasing oral health behavior self-efficacy, would best promote home care compliance (Buglar, White & Robinson, 2010).

Theory of Planned Behavior (TPB)

The TPB, reported by Ajzen (1991), has been depicted as a "flexible" model that describes certain elements that affect a person's intention to engage in behaviors (Dumitrescu, Wagle, Dogaru & Manolescu, 2011). These variables of attitude, knowledge, subjective norm, and self-efficacy theoretically determine the person's willingness to engage in behaviors that will eventually lead to improved health status (Azjen, 1991). Dumitrescu and colleagues (2011) modeled the TPB to improve oral health behaviors among 153 medical students. A 56-question survey evaluated participants' current oral hygiene behaviors, behavior intention, affective attitude towards behavior, cognitive attitude towards behavior, subjective norms, perceived behavioral control, and oral health knowledge. Statistical analysis revealed that three of the variables (attitude, knowledge, and self-efficacy) were significant predictors of patients'

intentions to participate in oral behavior. Knowledge emerged as predictor to the subjects' desires to engage in oral health behaviors.

Social Learning Theory and Locus of Control

In 1966, Rotter presented a construct of the Social Leaning Theory (SLT), locus of control. The underlying premise of SLT is reinforcement, or reward, is essential to an individual's acquirement and achievement of skills and knowledge. Each individual perceives the reward or reinforcement differently. The potential will depend on (1) "whether or not the person perceives a causal relationship between his own behavior and reward," (2) the expectation of reward and reinforcement, and (3) the value of the reinforcement (Rotter, 1966). Wallston (1992) described SLT as an 'expectancy-value theory.' Reinforcement strengthens the expectancy that future reinforcement will occur if one holds value in the reinforcement or reward. For example, a patient who notices diminished halitosis from brushing will be more likely to brush in the future, should they value an odor-free oral cavity. As stated above, the perception of the causal relationship can affect their beliefs and behavior; therefore, some individuals perceive the reinforcement being a result of fate, chance, or another's actions. Rotter describes this person as having beliefs in external control or external expectancy for reinforcement. Meanwhile, those who attribute reward to their actions are said to have belief in internal control. Thus, the measurement of internal and external control (I-E scale) was developed as a generalized expectancy. A generalized expectancy is a characteristic that an individual will apply to all circumstances. However, even Rotter (1966) acknowledged "specific expectancies regarding the causal nature of behavior-outcome sequences in different situations would also affect behavior choice."

Wallston and colleagues (1976) identified the need for a specific Health Locus of Control (HLC) scale. A more specific expectancy affords the opportunity to predict behavior in specific situations. Its main purpose is to measure the individual's beliefs that health is controlled by either internal or external expectancies. This measurement of HLC was still similar to a generalized expectancy and unable to produce consistent findings across multiple health conditions. Two years later, Wallston (1978) developed a Multidimensional Health Locus of Control (MHLC). The MHLC scale provides researchers with the capability to subdivide externals into subgroups and study disease-specific expectancies utilizing 'Form C' (Wallston, Stein & Smith, 1994). The three dimensions MHLC scale divides locus of control into three dimensions: (1) internality (IHLC), (2) powerful others (PHLC), and (3) chance (CHLC; Wallston, 1978). Form C further subdivides PHLC into doctors (DHLC) and others (OHLC) as a more specific external expectancy (Wallston, Stein & Smith 1994). The MHLC and HLC scales have been utilized as a valid (Wallston, 2005) questionnaire to study a multitude of health conditions.

CHAPTER III: MATERIALS AND METHODS

Methodology

This study will survey current active duty personnel to ascertain the level of their knowledge of oral health utilizing a recently developed SOHKA, and correlate that knowledge with (1) their recent history of dental caries and periodontal disease, (2) their oral health-related behaviors and (3) their current risk of dental caries and periodontal disease. Individual risk status for dental caries and periodontal disease will be collected in accordance with US Navy Bureau of Medicine and Surgery Instruction 6600.16a (Oral Disease and Risk Management Protocols in the Navy Medical Healthcare System, Appendix A).

Additionally, active duty personnel will be surveyed for health locus of control and correlate locus of control with (1) their level of knowledge, (2) their oral health-related behaviors, (3) their recent history of dental caries and periodontal disease, and (4) their current risk of dental caries and periodontal disease.

The study consists of Phase I (pilot testing of the SOHKA to determine reliability and validity) and Phase II (validation of the SOHKA). Participants must be active duty personnel. Up to 312 volunteers will be recruited during Phase I and up to another 556 more subjects will participate in Phase II for a total of up to 868 subjects. Subjects will be recruited when they present for annual dental examinations or treatment at the Primary Care Dental Clinic (PCDC), WRNMMC. Through a web-based program (https://www.research.net/s/WRNMMCOralHealth; https://www.research.net/s/WRNMMCOralHealthPilot), participants will take the survey containing 15 demographic and self-reported behavior questions (Appendix B), the 28-

SOHKA question (Appendix C), and the 18-question MHLC specific for oral health (Appendix D). We expect that the survey will take subjects less than 20 minutes to complete. We will then review the participants' dental records to determine if either survey accurately predicts current oral health status, using the caries risk and periodontal diseases risk management protocol.

Study Design

Phase I – Pilot testing of the SOHKA to determine reliability and validity: Up to 312 subjects will be recruited to complete the study plan as described in the previous paragraph. Of the 312 subjects, approximately 100 subject's records will be reviewed and data collected for disease status/risk. All other subjects will only be administered the web-based survey to collect SOHKA and MHLC data. Data will be reviewed and the SOHKA survey may be revised (i.e. questions will be edited or deleted) prior to initiation of Phase II.

- In Phase I participants can elect to provide informed consent to complete the web based survey and have their dental record assessed for oral health risks or they can elect to simply complete the survey and not have their dental record assessed.
- During Phase I through WRNMMC PostMaster active duty members can also choose to complete the surveys online at a home/work computer.

Phase II – Validation of the SOHKA: Up to 556 more subjects will provide informed consent to complete the study plan as described above using the revised version of the SOHKA.

Participants who provide informed consent during Phase I and Phase II will have their dental records abstracted for caries risk, periodontal risk, and 3 years caries incidence utilizing the past three dental examinations.

Study Population, Inclusion and Exclusion Criteria

Subjects will be male and female active duty patients of the WRNMMC PCDC. All active duty personnel whose dental records are held at this facility will be eligible to participate in this study.

a. Inclusion Criteria

1) All male and female military active duty personnel whose dental records are held at WRNMMC PCDC will be eligible to participate in this study.

2) Participants dental records must contain documentation of at least three annual dental examinations.

b. Exclusion Criteria

1) Subjects whose dental records are not held at WRNMMC Primary Care Dentistry.

2) Subjects whose dental records do not contain documentation of at least three annual dental examinations.

3) Subjects who participate in Phase I data collection will not be allowed to participate in Phase II.

4) Subjects who participate via the web-based link in Phase I will be asked to not participate at the PCDC. Participants who participate at the PCDC will be asked to not complete the survey via the web-based link.

Sample Size Estimation

Phase I (pilot test): A sample of up to 312 subjects will be required to complete the SOHKA to allow for testing the internal consistency. Based on a 10:1 ratio of subjects: the number of questions for factor analysis, and a total of 28 questions in the SOHKA, we will need 280 completed questionnaires. To allow for a 10% dropout rate, up to 312 subjects will be surveyed. We will collect complete data (i.e. health status from the dental record) for up to 100 consecutive subjects who complete the survey in the clinic in order to accrue at least 10 subjects who are at high risk of periodontal disease (see chart below for assumptions)

Phase II (SOHKA validation): To estimate the minimum number of subjects needed to detect an association between survey results and 1) caries risk (rated as low, moderate, or high) and 2) periodontal disease risk (rated as low, moderate, or high), the following distribution of subjects in risk categories is assumed based on our past clinic experience.

	High Risk	**Moderate Risk**	**Low Risk**
Dental Caries	25%	45%	30%
Periodontal	10% (conservative estimate)	60%	30%

Testing the null hypothesis that the correlation coefficient is r = 0: Controlling the probability of a Type I error at alpha = 0.05, a sample of 85 subjects would have 80% power to detect a correlation coefficient of at least r = 0.30; a sample of 194 subjects would have 90% power between the SOHKA and risk status. To extend the analysis and explore multiple factors that may be associated with high risk status, we will consider the expected 10% high risk rate of periodontal disease, as this would be the outcome category with the fewest number of subjects. If, for example, a logistic regression analysis for high risk of periodontal disease were to be explored, we would want to accrue a minimum of 10-20 high risk subjects per independent variable in the model. A sample of 500 subjects would therefore provide 50 high risk subjects and we could explore at least 4-5 independent variables in a multivariate model of periodontal risk.

To allow for dropouts or incomplete medical records (e.g. ~10% loss rate), up to 556 subjects will be recruited for Phase II of this protocol. Based on our current caseload, we anticipate that there will be 40-50 eligible subjects per clinic day, and therefore accruing up to 868 subjects (312 in Phase I + 556 in Phase II = 868 total subjects) is feasible

Data Analysis Plan

1. For each phase (Phase I and Phase II) of the study, demographic and clinical characteristics of the sample of subjects in each Phase will be presented using means with standard deviations, medians with ranges or counts with proportions.

2. Phase I:

    a. Data for the MHLC-Form C and SOHKA surveys will be examined using factor analysis; internal consistency will be examined using Cronbach's alpha,

and the range, mean and standard deviations will be presented. We will explore possible subscales for the SOHKA (i.e. behavioral subscales and knowledge subscales) as well as a total score.

b. The MHLC-Form C survey results will be scored for each subject on a scale from 6-36 for each of the three subscales for this survey: the IHLC, the CHLC and the PHLC. The PHLC is further categorized into two subscales scored from 3-18. These subscales for the PHLC are the OHLC and the DHLC. (see Appendix F for scoring methodology). Scores will be summarized using means with standard deviations or medians with interquartile ranges.

c. Association of the MHLC-Form C subscales and SOHKA subscales will be explored using Pearson's correlation coefficient. Association of the MHLC-Form C subscales and SOHKA subscales with caries risk status and periodontal disease risk status will be explored using analysis of variance. Initial hypotheses will be generated from this pilot phase.

3. Phase II:

a. The MHLC-Form C and SOHKA surveys will be scored (subscales or a total score for the SOHKA will be determined from Phase I). We will generate descriptive statistics (mean, median, range) for each score by demographic characteristics (age groups, gender, race, education), tobacco use, caries risk status, and periodontal disease risk status.

b. For each most recent caries risk category (Low, Moderate, High), we will calculate the following:

Median (interquartile range (IQR) number of new caries lesions at each annual examination;

Median (IQR) three-year caries incidence;

Mean (± SD) MHLC-Form C subscale scores and SOHKA survey scores (total, behavioral subscales and knowledge subscales). Scores in the three risk groups will be compared using analysis of variance.

c. For each most recent periodontal risk category (Low, Moderate, High), we will describe the following:

Mean (± SD) and highest PSR sextant score at each annual examination;

Mean (± SD) three-year PSR sextant score and mean (± SD) three-year highest PSR sextant score; PSR scores will be evaluated for missing data and consistency of results after Phase I to determine if this data will continue to be collected in Phase II.

Mean (± SD) MHLC-Form C subscale scores and SOHKA survey scores (total, behavioral subscale and knowledge subscale). Scores in the three risk groups will be compared using analysis of variance.

Additional outcomes are the number of caries at the current visit and the total number of caries over the past 3 years. These outcomes will be correlated with the 6 questions regarding behavior using Kruskal Wallis analysis of variance.

Further, we will estimate associations between the MHLC-Form C and SOHKA survey scores and Gender, Age, Race, Education, and Behavior (brushing, flossing, tobacco use, and snack consumption) based on the two sample t-test and Pearson's or Spearman's correlation coefficient.

Data analysis is primarily exploratory given the low incidence of periodontal caries. Multivariate analysis of significant demographic indicators for survey scores will be explored using linear regression. We will calculate Pearson's correlation coefficient to measure the level of agreement between MHLC-Form C and SOHKA survey scores. To explore the association of demographic and clinical variables, oral health knowledge survey results and locus of control survey results with oral health status (either caries or periodontal), ordinal logistic regression analysis will be used with a model using caries risk as the dependent variable and a separate model using periodontal risk as the dependent variable. All statistical significance levels will be set at $\alpha = 0.05$. All data analyses will be completed using Statistical Package for the Social Sciences (SPSS) Version 18 software (SPSS, Inc., Chicago, IL).

Study Limitations: Given the fixed order of the surveys, it is possible that the last survey may have less complete responses. Also, generalizability of this research is limited based on the specific characteristics of the study population.

CHAPTER IV: RESULTS

The Walter Reed National Military Medical Center Institutional Review Board approved this project in May 2015. No data is available to analyze. It is expected to examine relationships between behavior, knowledge, locus or control and oral health status. The project will be continued by a future Comprehensive Dentistry Resident. It is expected to take 2 years to collect all data.

CHAPTER V: DISCUSSION

Locus of control scales are administered to dental patients to understand their oral disease preventative behaviors. The studies of oral behaviors are limited. However, patients with chronic conditions have demonstrated a slight correlation between IHLC and PHLC (Wallston, Stein & Smith, 1994) and increased power in predicting behaviors (Wallston, 1981). This is potentially due to the close management needs of patients with chronics condition, such as Diabetes and Cardiovascular Disease, by medical or dental professionals. This is observed in studies of diabetic patients, who felt doctors were responsible for their health conditions getting better (Wallston, 2005). Due to the chronic nature of dental caries and periodontal disease, one might expect to collect similar findings.

Ludenia and colleagues (1982) examined the relationship between locus of control, oral hygiene, and periodontal disease. A total of 101 male participants, with a mean age of 53.22 were administered the MHLC Form B scale, Strait-Trait Personality Inventory, and Beck Depression Inventory while being evaluated for oral hygiene status (based off examination, rated on 4-point scale), and degree of periodontal disease (also a 4-point scale from examination). The patients studied did not differ statistically when scored either as 'externalists' or 'internalists' ($p>0.05$) for oral health status and age. Yet, older patients in the study were associated statistically with 'Powerful Others Externality' ($p<0.001$), implying patients tend to rely/trust doctors more as they age. These results are similar to results seen in studies by Wallston and Wallston (1981) and Carnahan (1979) in which patients were assessed for brushing, flossing, and sugar consumption. Carnahan, however, developed a dental-condition-specific locus of control scale that also

did not predict oral hygiene practices. Prediction of preventative behaviors has not been done successfully utilizing the MHLC scales (Forms A/B). Wallston (1981) attributed this to "highly learned habits," such as brushing, having "little to do with most people's conception of health and illness."

Odman (1984) collected similar results in a study of 22 patients with moderate periodontitis at the University of Minnesota, Department of Periodontology. The study administered the Nowicki-Strickland Locus of Control Scale for Adults, rather than the MHLC. Data was collected to measure locus of control scores, oral health status (O'Leary) and brushing and flossing skill. Each participant was evaluated at baseline and following initial periodontal therapy. No statistical relationship was seen between internal or external locus of control, behavior, and health status.

There have been studies that have seen correlations between MHLC and oral health determinants. A study consisting of 60 participants (46 females and 14 males) were examined to observe correlations between MHLC Form A and results to an oral hygiene program. Each participant received an oral examination assessing plaque (O'Leary) and gingival inflammation. Prior to the second appointment, participants completed Part A of the MHLC questionnaire. Then one of two hygienists educated patients, administered oral hygiene instruction and provided a dental prophylaxis (scaling and polishing) at weeks 0, 3, 6, 10 and 18. Patients were given their oral health index scores each appointment to observe treatment advancement. Participants with higher PHLC scores were statistically associated ($p<0.01$) with better plaque index score changes between baseline and 18 weeks. Meanwhile, IHLC was also associated with 18-week plaque change ($p<0.03$), along with decreases in gingival inflammation after 10

weeks ($p<0.04$). The authors discussed that PHLC patients had better compliance because they were more "receptive" to advice. IHLC participants were associated as expected in HLC theory (Galgut, Waite, Todd-Pokropek & Barnby, 1987). Stenstrom (2009) observed increased gingivitis in patients (n=181 university students) with higher PHLC. This is attributed to patients relying on professionals for defensive treatment of oral diseases, rather than actively participating daily in preventative behaviors.

In Finland, Kneckt and colleagues (1999) studied the correlation of locus control with both diabetes and oral health. They attempted to determine the predictability of locus of control on behaviors and health status in 149 diabetics (type-1). Data collection consisted of measuring glycosylated hemoglobin (HbA1c), plaque, gingival inflammation, decayed surfaces, Dental Coping Belief Scale (locus of control scale), specific health values, diabetes locus of control scale, and reported behaviors. Diabetes locus of control was not statistically associated with health behaviors ($p>0.05$) or HgA1c ($p>0.05$), despite diabetes locus of control being correlated with dental locus of control ($p=0.0005$) and dental locus of control being statistically associated with both oral health status and behavior. Specifically, internal locus of control was associated with less plaque ($p=0.034$, decayed surfaces ($p=0.006$), and root caries ($p=0.009$).

Acharya and Sangam (2008) looked at the correlation of oral health-related quality of life and HLC in a university (dental school) setting. A questionnaire was administered to 372 undergraduate dental students in India measuring MHLC Form B, Oral Health Impact Profile (OHIP-14), a measure of oral health quality of life, and self-reported oral status. The study was a cross-sectional, prospective study based off the year of study in dental school each participant was currently in (4 years). The study focused

on the impact of oral health quality of life and oral health status, however, a statistically significant relationship was observed between OHIP-14 and CHLC (chance; $p<0.01$). Participants that did not engage in oral hygiene behaviors because they perceived their problems being associated by fate, chance, or luck, resulted with higher OHIP-14 scores (poor perceived oral health quality of life). Each year, students increased their perception of oral health quality of life. This can possibly be attributed to increases in knowledge. Therefore, knowledge may have a direct effect not only oral health quality of life, but also locus of control.

The mechanisms linking literacy, knowledge, behavior, and oral health status have not been studied as comprehensively compared to general health. Yet, a relationship still appears to exist amongst knowledge, behavior, and oral health status. As identified earlier, knowledge is a predictor of an individual's intention to improve oral health behaviors (Dumitrescu, Wagle, Dogaru, & Manolescu, 2011). Because studies have identified a lack of knowledge regarding behaviors associated with oral health status in the general population (Corbin, Maas, Kleinman, & Backinger, 1987), it highlights the necessity to better understand the mediators of these determinants.

The predominance of literature shows a mixed relationship between knowledge and behavior. Hamilton and Coulby (1991), who studied children, along with Lin and colleagues (2001), who studied adults, established a relationship between high knowledge and its correlation to engaging in oral health behaviors. On the contrary, Freeman and colleagues (1993), Al-Ansari (2003), and Suprabha and colleagues (2013) did not ascertain statistically significant relationships between dental knowledge and oral health behaviors.

Lee and colleagues (2012) interviewed 1,405 women enrolled in the Carolina Oral Health Literacy Project to assess oral health literacy (REALD-30), oral health status (self-reported NHANES item), behavior (Dental Neglect Scale) and self-efficacy (General Self-Efficacy Scale). The aim of this study was to discern an association between oral health literacy, status, and behavior. The authors reported the following results: (1) Better oral health literacy is associated with improved oral health status; (2) worse behaviors (higher Dental Neglect Scale scores) were correlated with poor oral health status. This positive correlation between oral health behaviors and oral health status was also seen in studies of children (Chu, Ho, & Lo, 2012), college students (Kumar& colleagues 2010), and young adults (Levin & Shenkman, 2004). However, oral health behavior was not associated with low DMFT scores ($p > 0.1$) in the study of Canadian children by Hamilton and Coulby (1991).

Ronis, Antonakos and Lang (1996) described the usefulness of various factors in predicting oral health behaviors. They administered a 50-minute survey to 662 subjects in the Detroit tri-county area and studied the correlation between criterion variables (e.g., brushing frequency), general dental perception variables (e.g., knowledge and perceived severity), and behavior-specific variables (e.g., barriers, influences and self-efficacy). Flossing was associated with more behavior-specific variables, while brushing was largely predicted by demographic variables. While our understanding of oral health behavior is increasing, the application of behavior theory and understanding of determinants of behavior, to long-term maintenance of behaviors that will improve oral health status is incomplete. Further understanding of the determinants surrounding these

complex theories is required before we can effectively identify, predict, and manage patient appropriately.

CHAPTER VI: CONCLUSION

The level of oral health literacy is undoubtedly important due to its effect on health outcomes. The effects of low literacy do not exist only within the individual, but also impact the health care system. For that reason, it is important to understand the factors that mediate literacy to health outcomes. Oral health literacy, if understood fully, might provide the dental profession with the means to identify patients with compromised oral health, improve access to care, increase patient confidence in navigating the oral health system, ensure proper utilization of dental care, develop patient provider-communication, and produce patients with self-efficacy, engaged in their own self-care. The problem is that oral health literacy is a multifaceted concept, dependent upon an already complex health system, patient-provider communication, and chronic disease self-care.

Thus, other factors need to be more closely examined in this relationship. The relationship between behavior and health status is more definite. Locus of control, an overwhelmingly studied determinant of behavior, shows promise in predicting oral health behaviors. Previous studies have varied results when attempting to study the correlation between locus of control and oral health behaviors, such a brushing. Nonetheless, most of the studies measured locus of control with either the HLC or MHLC (Form A/B) scales. Form C provides a multidimensional study of locus on control that is domain specific to oral diseases.

What we also do not know is how much of an effect having high or low comprehensive knowledge has on mediating, locus of control and oral health status. To

date, no study has attempted to study the correlation between oral health knowledge and locus of control. Therefore, it would be noteworthy to better understand the complex relationships of knowledge and behavior to oral health status in a more diverse population. We would like to administer a survey that addresses oral self-care, oral disease etiology, and prevention (SOHKA), disease specific locus of control (Form C), reported behaviors, and oral health status. Further understanding of these determinants not only enhances the individual but also the community.

APPENDIX A: BUMED INSTRUCTION 6600.16A-Caries/Periodontal Risk

DENTAL CARIES RISK MANAGEMENT PROTOCOL

1. A Caries Risk Assessment will be performed on all active duty dental patients during the annual and periodic oral examination and recorded on the NAVMED 6600/13 Oral Exam. Patients will be classified as low, moderate, or high risk for future caries experience per the following Tri-Service criteria:

a. Low Caries Risk patients exhibit the following (must satisfy all criteria below):

(1) No new incipient or cavitated primary or secondary carious lesions during current exam.

(2) No factors that may increase caries risk. Factors increasing risk of developing caries may include, but are not limited to:

(a) Poor oral hygiene.

(b) Cariogenic diet.

(c) Presence of exposed root surfaces.

(d) Enamel defects or genetic abnormality of teeth.

(e) Many multisurface restorations.

(f) Restoration overhangs or open margins.

(g) Active orthodontic treatment.

(h) High titers of Cariogenic bacteria.

(i) Chemotherapy or radiation therapy.

(j) Eating disorders.

(k) Physical or mental disability with inability or unavailability of performing proper oral health care.

(l) Suboptimal fluoride exposure.

b. Moderate Caries Risk patients exhibit the following (demonstration of any single criterion necessitates an assessment of Moderate Caries Risk):

(1) One or two new incipient or cavitated primary or secondary carious lesions during current exam.

(2) No incipient or cavitated primary or secondary carious lesions during current exam but presence of at least one factor that may increase caries risk as outlined in paragraphs 1a(2)(athrough 1a(2)(l) above.

c. High Caries Risk patients exhibit the following (demonstration of any single criterion necessitates an assessment of High Caries Risk):

(1) Three or more new incipient or cavitated primary or secondary carious lesions during current exam.

(2) Presence of multiple factors that may increase caries risk as outlined in paragraphs 1a(2)(a) through 1a(2)(l) above.

(3) Xerostomia (medication-, radiation- or disease-induced).

2. Determination of caries risk classification will prompt treatment protocols specific to the risk category. Required educational and treatment protocols for each caries risk category are summarized in the following table on the next page, and must be uniformly implemented throughout Navy Dentistry.

CARIES RISK MANAGEMENT PROTOCOL FOR NAVY DENTISTRY

Low Caries Risk	Moderate Caries Risk	High Caries Risk
1. Oral hygiene Instruction. 2. Fluoride Dentifrice.	1. Oral hygiene instruction and oral disease education using this instruction, enclosure (7) as an outline. 2. Fluoride dentifrice. 3. Caries elimination a. Sealants for pits and fissures judged at risk. b. Incipient caries remineralization. 4. Identification of patient specific dietary modification (nutritional counseling). 5. Professional topical fluoride treatment (at 6 month interval); may be accomplished concurrently with restorative treatment). 6. Home fluoride rinses (OTC) or home fluoride treatments using prescription dentifrices, gels or pre-fabricated trays. 7. Discuss benefits of Xylitol chewing gum and provide a sample if available.	1. Oral hygiene instruction and oral disease education using this instruction, enclosure (7) as an outline. 2. Fluoride dentifrice. 3. Caries elimination a. Sealants for pits and fissures judged at risk. b. Incipient caries remineralization. 4. Identification of patient specific dietary modification (nutritional counseling). 5. Professional topical fluoride treatment (four applications over 6-12 months; may be accomplished concurrently with restorative treatment). 6. Home fluoride rinses (OTC) or home fluoride treatments using prescription dentifrices/gels or pre-fabricated trays. 7. Discuss benefits of Xylitol chewing gum and provide a sample if available. 8. Antibacterial mouth rinses. 9. Bacterial testing (if available). 10. Evaluation of salivary flow.
One Year Recall	6-12 Month Recall	3-Month Recall

PERIODONTAL DISEASES RISK MANAGEMENT PROTOCOL

1. A Periodontal Disease Risk Evaluation will be performed on all active duty dental patients during the annual or periodic oral examination and recorded on the NAVMED 6600/13. Patients will be classified as low, moderate, or high risk for development of periodontal disease per the following risk factors:

    a. Periodontal Screening and Recording (PSR) Score. Among clinical parameters, probing depths of 3.5 mm or more (PSR 3 or 4) may be predictive of subsequent attachment loss. Therefore, PSR scores are the primary indicator of future periodontal diseases risk.

    b. Tobacco Use. Smokers are four to five times more likely to have periodontal diseases than non-smokers. Spit tobacco use (sometimes referred to as smokeless tobacco) increases the risk of localized gingival recession, caries, and oral cancer.

    c. Genetic Susceptibility. Assessed by asking the patient if any of his or her immediate family have lost teeth at an early age, have had treatment for periodontal disease, or has a history of diabetes.

    d. Oral Hygiene. Inadequate oral hygiene is predictive of gingivitis and mild to moderate chronic periodontitis.

    e. Past history of periodontal treatment.

2. Determination of periodontal risk classification will prompt treatment protocols specific to the risk category. Required educational and treatment protocols for

each periodontal risk category are summarized in the table below, and must be uniformly implemented throughout Navy Dentistry.

PERIODONTAL DISEASES RISK MANAGEMENT PROTOCOL

LOW PERIO RISK	MODERATE PERIO RISK	HIGH PERIO RISK
• *PSR 0, 1, or 2*	• *PSR 3* • Less than two additional risk factors.	• *PSR 4* • *PSR 3* (Plus any two of the following) - Tobacco user. - Inadequate oral hygiene. - Family history of tooth loss or diabetes. - Past history of periodontal treatment.
RISK MANAGEMENT	**RISK MANAGEMENT**	**RISK MANAGEMENT**
• Annual exam by general dentist and prophylaxis as needed by trained auxiliary.	• Annual exam by a general dentist and prophylaxis by a dental hygienist. • Recall based on individual patient needs. • Evaluation and discussion of periodontal disease risk factors.	• Referral for comprehensive exam by a periodontist or equivalent and prophylaxis by a dental hygienist. • Recall based on individual patient needs. • Evaluation and discussion of periodontal disease risk factors.

APPENDIX B: DEMOGRAPHIC AND BEHAVIOR QUESTIONS

1) Currently Active Duty?
    a. Yes
    b. No

2) Continuously Active Duty for the past 36 months or longer?
    a. Yes
    b. No

3) Branch of service:
    a. Army
    b. Navy
    c. Air Force
    d. Marines
    e. Coast Guard
    f. Public Health Service
    g. National Guard
    h. N/A

4) Rank (or final rank if retired)
    a. E1-E3
    b. E4-E6
    c. E7-E10
    d. O1-O3
    e. O4-O6
    f. O7-O10
    g. Non military

5) Age:
    a. 16-18
    b. 19-24
    c. 25-39
    d. 40-49
    e. 50-64
    f. 65 and older

6) Educational level:
    a. Less than high school
    b. Some high school
    c. High school graduate
    d. GED or high school equivalency
    e. Some college, less than 2 years
    f. Associates degree
    g. Some college, 2 or more years, no degree
    h. Bachelors degree
    i. Some postgraduate training, no degree
    j. Postgraduate degree

7) Gender:
    a. Male
    b. Female

8) What is your race/ethnicity? Please choose one or more
    a. White
    b. Black or African-American
    c. Hispanic or Latino
    d. Asian
    e. Native Hawaiian or other Pacific Islander
    f. American Indian or Alaska Native
    g. Other

9) Reason for today's visit:
    a. Annual exam
    b. Hygiene appointment
    c. Dental filling or other dental procedure appointment
    d. Walk-in or sick call

10) How often do you brush your teeth?
    a. Less than 1 time per week
    b. 1-2 times per week
    c. Most days but not everyday
    d. At least 1 time every day
    e. More than 1 time every day

11) How often do you floss your teeth?

a. Less than 1 time per week
b. 1-2 times per week
c. Most days but not everyday
d. At least 1 time every day
e. More than 1 time every day

12) Do you use tobacco products?
a. Yes. I smoke cigarettes or cigars or a pipe
b. Yes. I use smokeless tobacco
c. No. I quit using tobacco products more than 3 months ago
d. No. I quit using tobacco products less than 3 months ago
e. No. I have never been a regular user or tobacco products

13) How often do you drink regular soda or eat sugary snacks between meals?
a. Less than 1 time per week
b. 1-2 times per week
c. Most days but not everyday
d. At least 1 time every day
e. More than 1 time every day

14) Is your dental knowledge today greater than it was 3 years ago?
a. Yes
b. No
c. I don't know

15) Is your oral hygiene better that it was 3 years ago?
a. Yes
b. No
c. I don't know

APPENDIX C: SOHKA QUESTIONNAIRE

SURVEY OF ORAL HEALTH KNOWLEDGE IN ADULTS

The following survey is designed to help us understand what people know about their dental health.

All of the questions are true and false or multiple-choice. Please answer all questions and it is appropriate to answer with the choice "I don't know".

16) Bacteria that cause dental cavities can be spread from mother to child through contact with the mother's saliva by sharing food or kissing.
    a. True
    b. False
    c. I don't know

17) Stimulating saliva flow protects your teeth.
    a. True
    b. False
    c. I don't know

18) Snacks that are low in carbohydrates are less likely to cause dental cavities.
    a. True
    b. False
    c. I don't know

19) Snacks like carrots and apples are as likely to cause dental cavities as snacks such as cake and cookies.
    a. True
    b. False
    c. I don't know

20) Dry mouth, a side effect of many medications and chronic diseases, is a factor in
    a. Developing dental cavities.
    b. True
    c. False
    d. I don't know

21) Carbonated beverages that do not contain sugar (like Diet Coke) have no effect on teeth.
    a. True
    b. False
    c. I don't know

22) Which of the following does not cause dental cavities?

a. table sugar
b. fruit juice
c. milk
d. artificial sweetener
e. corn syrup
f. I don't know

23) Dental cavities usually grow beneath the surface of the teeth before becoming a hole on the surface.

a. True
b. False
c. I don't know

24) Dental caries refers to

a. The decay (carious) process
b. The lesion that results from the decay process
c. both a and b
d. neither a and b
e. I don't know

25) Which of the following practices most increases your risk of getting dental cavities?

a. Sipping from a sugary soft drink all afternoon
b. Drinking a sugary soft drink at a meal
c. Both practices are equally risky
d. I don't know

26) Drinking tap water containing _____ may protect your teeth from getting dental cavities.

a. Fluoride
b. Iron
c. Vitamin C
d. Vitamin D
e. I don't know

27) Dental sealants prevent:

a. food particles from getting in between the teeth
b. teeth from getting stained
c. gum disease
d. dental cavities
e. I don't know

28) The ideal time to get dental sealants is:
a. When baby teeth first appear in the mouth
b. When enamel on permanent teeth is fully visible above the gum line
c. When enamel on permanent teeth has been visible above the gum line for 3-5 year
d. I don't know

29) Tooth brushing reduces dental cavities by breaking up plaque above the gum line.
a. True
b. False
c. I don't know

30) Tooth brushing with more force is a good practice because it leaves the teeth cleaner.
a. True
b. False
c. I don't know

31) Flossing controls gum disease by breaking up plaque below the gum line.
a. True
b. False
c. I don't know

32) If flossing makes your gums bleed, you should not floss.
a. True
b. False
c. I don't know

33) The same kind of plaque that causes dental cavities causes gum disease.

a. True
b. False
c. I don't know

34) Smoking tobacco affects oral cancer but not gum disease.
a. True
b. False
c. I don't know

35) Smokeless tobacco has no effect on gum disease or dental cavities.
a. True
b. False
c. I don't know

36) Gum disease may make it more difficult for a diabetic patient to control their blood sugar.
a. True
b. False
c. I don't know

37) Gum disease may be more severe in people with poor nutrition.
a. True
b. False
c. I don't know

38) Some orally transmitted viruses may cause oral cancer.
a. True
b. False
c. I don't know

39) Stress may contribute to dental disease and mouth sores.
a. True
b. False
c. I don't know

40) Expert tooth brushing is enough to prevent dental cavities and gum disease.

a. True
b. False
c. I don't know

41) Skin replaces itself every 30 days. Soft tissue covering the inside the mouth replaces itself in 15 days.

a. Both statements are true
b. The first statement is true, the second statement is false
c. The first statement is false, the second statement is true
d. Both statements are false
e. I don't know

42) Sinus congestion can cause toothaches.

a. True
b. False
c. I don't know

43) Jaw muscle pain can cause toothaches.

a. True
b. False
c. I don't know

APPENDIX D: MHLC FORM C-ORAL HEALH QUESTIONNAIRE

Instructions: Each item below is a belief statement about your health condition with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to select the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you select. The more you disagree with a statement, the lower will be the number you select. Please make sure that you answer **EVERY ITEM** and that you select **ONLY ONE** number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers

44	If my oral health worsens, it is my own behavior, which determines how soon I will get better again.
45	As to my condition, what will be, will be.
46	If I see my dental professional regularly, I am less likely to have problems with my oral health
47	Most things that affect my oral health happen to me by chance.
48	Whenever my oral health worsens, I should consult a dentally trained professional.
49	I am directly responsible for my oral health getting better or worse.
50	Other people play a big role in whether my oral health improves, stays the same, or gets worse.
51	Whatever goes wrong with my oral health is my own fault.
52	Luck plays a big part in determining how my oral health improves.
53	In order for my oral health to improve, it is up to other people to see that the right things happen.
54	Whatever improvement occurs with my oral health is largely a matter of good fortune.
55	The main thing, which affects my oral health, is what I myself do.

56	I deserve the credit when my oral health improves and the blame when it gets worse.
57	Following dentist's orders to the letter is the best way to keep my oral health from getting any worse.
58	If my oral health worsens, it's a matter of fate.
59	If I am lucky, my oral health will get better.
60	If my oral health takes a turn for the worse, it is because I have not been taking proper care of myself.
61	The type of help I receive from other people determines how soon my oral health improves.

APPENDIX E: MHLC FORM C-ORAL HEALH QUESTIONNAIRE SCORING

SUBSCALE	POSSIBLE RANGE	ITEMS
Internal	6 - 36	44,49,51, 55,56,60
Chance	6 - 36	45,47,52, 54, 58, 59
Powerful Others	6 - 36	46,48,50, 53,57,61
Doctors	3 - 18	46,48,57
Other People	3 - 18	50,53,61

The score on each subscale is the sum of the values circled for each item on the subscale (i.e., where 1 = "strongly disagree" and 6 = "strongly agree"). No items need to be reversed before summing. All of the subscales are independent of one another.

APPENDIX F: DATA COLLECTION SHEET

Subject	1	2	3	4	5	6	7	8	…	500
Q1 *D										
Q2 *D										
Q3 *D										
Q4 *D										
Q5 *D										
Q6 *D										
Q7 *D										
Q8 *D										
Q9 *D										
Q10 *B										
Q11 *B										
Q12 *B										
Q13 *B										
Q14										
Q15										
New restorations needed year 1 caries										
New restorations needed year 2 caries										
New restorations needed year 3 caries										
Caries Risk Recent Exam										
Periodontal Risk Recent Exam										
Q16: 0 or 1										
Q17										
Q18										
Q19										
Q20										
Q21										
Q22										
Q23										
Q24										

Q25										
Q26										
Q27										
Q28										
Q29										
Q30										
Q31										
Q32										
Q33										
Q34										
Q35										
Q36										
Q37										
Q38										
Q39										
Q40										
Q41										
Q42										
Q43: 0 or1										
Q44: 1-6										
Q45										
Q46 *Doc										
Q47										
Q48 *Doc										
Q49										
Q50 *Other										
Q51										
Q52										
Q53 *Other										
Q54										
Q55										
Q56										
Q57 *Doc										
Q58										
Q59										
Q60										
Q61 *Other										
Knowledge Score: Sum Q16-43										
Total IHLC 6-36: Sum-Q:44,49,51, 55,56,60										
Total CHLC										

6-36: Sum-Q:45,47,52, 54, 58, 59										
Total PHLC 6-36: Sum-Q:46,48,50, 53,57,61										
Total DHLC 3-18 Sum-Q:46,48,57										
Total OHLC 3-18 Sim-Q:50,53,61										

APPENDIX G: INFORMED CONSENT

WALTER REED NATIONAL MILITARY MEDICAL CENTER (WRNMMC)
BETHESDA, MARYLAND

This consent form is valid only if it contains the IRB stamped date

Consent for Voluntary Participation in a Research Study Entitled:
Correlations between Oral Health Knowledge, Locus of Control, and Oral Health Status

Principal Investigator: *LT Andrew R. Knofczynski, DC, USN*
Comprehensive Dentistry Resident
Andrew.R.Knofczynski.Mil@Mail.Mil

Study site: X WRNMMC, __ FBCH, __USUHS, ___WRAIR, ___NMRC, ___JPC, ___OTHER

1. INTRODUCTION OF THE STUDY

You are being asked to be in this research study because you are active duty military and have had at least 3 annual dental exams in the military.

Taking part in this study is voluntary. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled. Leaving the study will not affect your medical care. Please read the information below, and ask questions about anything you do not understand, before deciding whether to take part in the study.

If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

2. PURPOSE OF THE STUDY:

The purpose of this study is to explore any associations of oral health knowledge and oral health beliefs with oral health status. In other words, this research will help us learn more about what our patients know about oral health and if our patients think that self-care or professional care is more important for keeping our mouths healthy. To be in this study you must be active duty and have had at least 3 annual dental exams in the military.

Other studies have shown that knowledge and locus of control (how much control over your health you have or think you have) are associated with behavior and potentially oral health status. No studies to date have looked at these factors utilizing an oral health disease specific questionnaire for locus of control.

3. PROCEDURES TO BE FOLLOWED:

If you decide to participate, please answer all 61 questions on the Survey of Oral Health Knowledge in Adults, the Locus of Control survey plus some questions on gender, age, education, rank, time in the military, etc. It takes about 20 minutes to answer all 61 questions on the computer. Your answers are uploaded to Survey Monkey and will be only identified by an individual study ID number. If you saw this survey on WRNMMC Postmaster and decided to complete it, please do not do the survey again.

Please do not ask other people for answers, or look up answers on your portable devices or share the questions with friends and colleagues. For this survey to benefit everyone, we need to know the baseline knowledge people have about these questions and not have anybody complete the survey twice.

After the survey, we will look in your dental record for information about your past dental cavity and gum disease experience. That is why at the end of the consent we ask you for your name and last 4 digits of your social security number. This information will be matched with your study ID number on a master list, and then it will be removed from your consent document that the investigators keep. After the cavity and gum disease information is collected, your name and last 4 digits of your social security number will be saved on the master list until all participant data has been collected. Then the master list will be destroyed.

You can elect to only complete the survey and not have your dental decay and gum disease risks assessed in your dental record. Your participation in the research will be finished following completion of the online survey.

4. ALTERNATIVES TO PARTICIPATION:

Choosing not to participate in this study (completing the questionnaire) is your alternative to participating for the study.

5. AMOUNT OF TIME FOR YOU TO COMPLETE THE STUDY

You will be finished with this study following completion of the online survey. After you consent, completing the survey takes about 20 minutes.

6. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY
A total of 868 patients will be enrolled in this study. It is only being conducted here at Bethesda.

7. POSSIBLE RISKS AND DISCOMFORTS FROM BEING IN THIS STUDY

There is no known health risk associated with completing the survey. There is a possible privacy risk is if master list that links your name and last 4 digits of your social security number were compromised. To prevent this from happening, the list containing this information will be protected by being kept in locked cabinets and on a password protected file on a CAC-enabled computer in the PI's office.

8. POSSIBLE BENEFITS FROM BEING IN THIS STUDY:

You may benefit from taking part in this study because your participation may increase your health knowledge. And your answers may help design future dental education programs that could improve dental health, reduce need for treatment, and save money. The information we collect may help us learn about further interventions to prevent and manage patients with dental disease.

However, no benefit can be guaranteed.

9. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep your research records. These records may be looked at by staff from the Walter Reed (WRNMMC) Department of Research Programs, the Walter Reed (WRNMMC) Institutional Review Board (IRB), the DoD Higher Level Review, and other government agencies.

These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your research records may be disclosed outside of WRNMMC, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to authorized research study personnel.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data. So, your name will not appear in any published paper or presentation related to this study.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

10. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you lose your right to receive dental care at a military hospital.

11. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You will not receive any payment for being in this study.

12. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE

You will not receive any compensation (payment) if you are injured as a direct result of being in this study. You should understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the study investigator before you enroll in this study.

Should you be injured as a result of your participation in this study, you will be given medical care for that injury at no cost to you.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in home care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations.

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the Human Protections Administrator, Department of Research Programs, at Walter Reed National Military Medical Center at 301-295-8273.

13. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY

There is no charge to you for taking part in this study.

14. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND THE INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the study investigator as soon as possible. By leaving this study at any time, you in no way risk losing your right to medical care and there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled.

Should you choose to withdraw, you must tell the investigators that you do not want to complete the survey.

15. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you. We are required to advise you how your PHI will be used. This authorization is effective until the end of the research study.

(1) What information will be collected?

For this research study, we will be collecting your name and the last 4 digits for your social security number so the investigators can match your dental decay and gum disease information from your dental record and the answers you provide on the survey.

(2) Who may use your PHI within the Military Healthcare System?

The members of the research team will have access to your health information in order to find out if you qualify to participate in this study, to administer research procedures, to monitor your progress, and/or to analyze the research data. Additionally, your PHI may be made available to groups such as the WRNMMC Department of Research programs and the WRNMMC Institutional Review Board.

(3) What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive your PHI?

No data is expected to be shared.

(4) What is the purpose for using or disclosing your PHI?

PHI will be used to collect information about oral health status from your dental records.

(5) How long will the researchers keep your PHI?

The master list, linking your study number and personal identifying information, will be destroyed as soon as data collection is completed. This action de-identifies the data so that it cannot be linked to you. The research team at the Naval Post-graduate Dental School will keep de-identified data indefinitely.

This consent form and HIPAA authorization and individual data files will be maintained for a period of six years after the study is completed and then destroyed.

(6) Can you review your own research information?

You may look at your personal research information at any time before your identifiers are permanently removed from the data.

(7) Can you cancel this Authorization?

Yes. If you cancel this Authorization, however, you will no longer be included in the research study. The study information collected prior to this cancellation will be used by the research team. No further data will be collected.

If you want to cancel your Authorization, please contact the Principal Investigator in writing:

Andrew R. Knofczynski
Naval Postgraduate Dental School
Walter Reed National Military Medical Center Building 1, 2nd Deck
8955 Wood Road
Bethesda, MD 20889-5628

(8) What will happen if you decide not to grant this Authorization?

If you decide not to grant this Authorization, you will not be able to participate in this research study. Refusal to grant this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

(9) Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the DoD Higher Level Review, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This

disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

(10) Who should you contact if you have any complaints?

If you believe your privacy rights have been violated, you may file a written complaint with the WRNMMC Privacy Officer, located at 8901 Wisconsin Ave, Bethesda, MD 20889, Telephone: 301-319-4775.

Your signature at the end of this document acknowledges that you authorize WRNMMC personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

16. CONTACTS FOR QUESTIONS ABOUT THE STUDY:

If you have questions about the study, or if you think you have a study-related injury you should contact LT Andrew Knofczynski at 301-319-4814 or LCDR Ling Ye at 301-295-0565. For questions about your rights as a research subject, contact the Human Protections Administrator, WRNMMC Department of Research Programs in Building 17 at 301-295-8273 or WRNMMC Staff Judge Advocate Office at 301-295-2215.

A signed copy of this consent form will be given to you.

SIGNATURE OF SUBJECT

You have read (or someone has read to you) the information in this consent form. You have been given a chance to ask questions and all of your questions have been answered to your satisfaction.

BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

SIGNATURE OF RESEARCH TEAM MEMBER OBTAINING CONSENT
My signature is intended to attest that the information in the consent document and any other information was explained to and apparently understood by the

subject that questions and concerns were addressed and that informed consent was freely given.

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject)

_____

Time

****

This sentence and the identifiers below will be removed from your consent as soon as the identifiers are entered on the master list.

Study #: _____
Your Name (please print):_____
Last 4: _____

APPENDIX H: PHASE I RECRUITMENT

"Correlations between Oral Health Knowledge, Locus of Control, and Oral Health Status"

This research will help us learn more about what our patients know about oral health and if our patients think that self-care or professional care is more important for keeping our mouths healthy. To be in this study you must be active duty.

Participation is voluntary. Not taking the survey is okay, and will not affect your access to treatment at this or any other treatment facility

Your participation may increase your health knowledge. And your answers may help design future dental education programs that could improve dental health, reduce need for treatment, and save money.

Please answer every question. Please do not ask other people for answers, or look up answers on your portable devices. Please do not share the questions with friends and colleagues. For this survey to benefit everyone, we need to know the baseline knowledge people have about these questions

If you choose to participate in the survey online please do not take the survey again while the research is being. Please share this link with other active duty personnel.

Link

https://www.research.net/s/WRNMMCOralHealthPilot

If you have questions about the study, or wish to see the answers, or if you think you have a study-related injury, use this page to contact Dr. Knofczynski, the Principal Investigator, at 301-295-4814. For questions about your rights as a research subject, contact the Human Protections Administrator, WRNMMC Department of Research Programs in Building 17 at 301-295-8273 or the WRNMMC Staff Judge Advocate Office at 301-295-2215.

THANK YOU FOR YOUR TIME. IT IS GREATLY APPRECIATED!

APPENDIX I: DESIGNEE RECRUITMENT SCRIPT

"While you are waiting for your appointment to start, may I give you some information to read about a research project we are conducting? If you decide to participate in the study, it will take about 20 minutes of your time, which in most cases is less than the time you will spend waiting for your appointment to start. If today is not a good day, you can choose to come back on another day OR take the survey at home (only Phase I). This is a voluntary study, if you choose not to participate; it will not affect your dental care."

"Have you already participated in the online survey via Postmaster link or receiving a link from the Dental Readiness Clinic"

If subject will participate and has not taken survey yet:

1) Give participant a Study ID #
2) Have participant fill out patient information on half sheet from consent
3) Set subject up with laptop
4) "Please return laptop upon completion of online survey"

If subject does not want to take laptop survey(during Phase I)

"Would you be willing to take the survey online at a personal computer in the near future?" (Show patient Appendix H)

If subject says yes. "Please take survey only once, do not take survey with others, or share questions/answers with friends. However, please share this sheet with other active service members. We are looking for 280 participants to take this survey."

Immediate return half-sheets, Mi-Fi units, and laptops to LT Knofczynski in-person to secure items*

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